EXHIBIT H

Medical & Scientific Opinions

Points of View on Lindane:

PROTECTION AGENCY

CENTERS FOR DISEASE
CONTROL AND PREVENTION

Jocelyn Elders, MD. Former US Surgeon General and Director of Health for the State
of Arkansas. Distinguished Professor of Pediatrics and Public Health at the University
of Arkansas for Medical Sciences. February 18, 2008.

ENVIRONMENTAL

Len I. Sweet, PhD, MPH, Msc. Senior Health Scientist, Chemrisk. University of

Michigan Alum of Toxicology, Environmental Science and Public Health Graduate

Programs. February 23, 2008.

Tor Shwayder, MD, Director, Pediatric Dermatology, Director, Dermatology Residency MEDICAL & SCIENTIFIC OPINIONS

OPINIONS

Program, Henry Ford Hospital, Detroit, Michigan, June 2007.

Adelaide A. Herbert, MD, Professor of Pediatrics and Dermatology, The University of

Texas Medical Shool at Houston; President, Society for Pediatric Dermatology, May 2007

Amy S. Paller, MD, Walter J. Hamlin Professor and Chair, Dept. of Dermatology, Professor of Pediatrics, Feinberg School of Medicine, Northwestern University, May

Amy S. Paller, MD, Walter J. Hamlin Professor and Chair, Dept. of Dermatology, Professor of Pediatrics, Feinberg School of Medicine, Northwestern University, May

Medical Society of the State of New York, March 2007

Medical Society of the State of New York, June 2005

Pharmacists Society of the State of New York, April 2006

U.S. Food and Drug Administration's (FDA) Response to Citizen's Petition, 1997

U.S. FDA Assessment Memorandum on Lindane, posted 2003

U.S. Centers for Disease Control and Prevention (CDC) Sexually Transmitted Disease Treatment Guidelines

U.S. Environmental Protection Agency (EPA) Evaluation of Carcinogenic Potential of Lindane. 2001

U.S. EPA Reregistration Eligibility Decision (RED), 2002

U.S. EPA Revised Assessment of Risk From Use of Lindane For Treatment of Lice and Scabies, July 2002

U.S. EPA Response to Comments on the 2002 Lindane RED, July 2006

World Health Organization Background Document on Lindane for Drinking-Water

Quality Guidelines, 2004

Please See Important Safety Information for Lindane Lotion and Shampoo

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Edward A. Krull, M.D. Chair Emeritus E. A. Krull Chair in Dermatologic Surgery (313) 916-2170

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Hair Ethan Nydorf, M.D. (313) 916-2168

Laser Therapy Ethan Nydorf, M.D. David Ozog, M.D. Mark Pomaranski, M.D. Tor Shwayder, M.D. (313) 916-2150

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Psoriasis Lubomira Scherschun, M.D. (313) 916-7679 DEPARTMENT OF DERMATOLOGY Henry Ford Medical Center New Center One

Rep. Rebekah Warren
Chair, Committee on the Great Lakes and the
Environment
P.O. Box 30014
Lansing, MI 48909

Re: House Bill 4569 regarding Lindane12 June 2007

Dear Rep. Warren and Honorable Members of the Committee,

I am director of Pediatric Dermatology at Henry Ford Hospital in Detroit. This letter concerns the above captioned bill mandating the banning and/or in-office use of topical medical-grade Lindane lotion. Let me put it succinctly: Lindane is safe, effective, it is not toxic if used as directed. I have used it repeatedly on many, many patients over the last 25 years without incident. I have even used it on myself, my children and my pregnant wife. It should continue to be available for pharmacy dispensation and home use by patients.

My training in both pediatrics and dermatology allows me to judge this issue. I am board certified in Pediatrics, in Dermatology and in the sub-specialty of Pediatric Dermatology. Since 1987 I have been director of Pediatric Dermatology at Henry Ford Hospital in Detroit. The University of Michigan Medical School taught the use of Lindane for scabies and lice during my training there. The same was true of my pediatric residency at U of M. Further training at University of Rochester Department of Dermatology (a second residency) reinforced the use of Lindane for both scabies and lice.

Lindane has been used on humans for over 60 years. Millions of doses have been applied to patients worldwide. It is still the number one treatment of choice in all of Central and South America, Africa, the Middle East, and Asia for head lice.

The literature does indeed document rare reported cases of percutaneous absorption leading to systemic symptoms. In over 90% of these cases the problem was overuse, misuse, drinking the lotion (!), or use of agricultural Lindane (20-30%) instead of medical Lindane (1%). It is important to separate these rare adverse events and place them as a numerator to the millions upon millions of doses used over the past 60 years. I once calculated how many prescriptions of Lindane I would have to write to encounter one adverse event unrelated to misuse. I chose the number of barrels of Lindane manufactured in a year and chose a ridiculously high adverse event rate. Estimating 45 seconds to write one Rx, I would have to write day and night 24 hours a day, 365 days a year for over 300 years to encounter one adverse event.

Are there alternatives to Lindane? Yes, of course. Each has its pluses and minuses. What is important is that insects become resistant to insecticides. Treatment-resistant lice exist in any given area that overuses a single prescription. Multiple treatment modalities are always needed. Lindane needs to remain as a physician-prescribed lotion or shampoo for home use.

This legislation also sets a very dangerous precendent. Why would or should a state committee unschooled in human metabolism, medicine, pharmacy or physiology ban or restrict an FDA approved medicine? Any information on a medicine's uses or adverse effects would be thoroughly studied by the FDA whose main function is to assure the safety of medicines prescribed in the whole USA.

I would be happy to present my testimony to your committee in person if you wish more in-depth analysis of the issues involved.

And that fetus exposed to Lindane when my wife used it, what happened to her? She just finished her freshman year at Harvard with stellar grades in high-level courses. Don't let these alarmist anti-Lindane

advocates scare you into thinking Lindane is a dreadful neurotoxin. It just isn't so.

Sincerely,

Tor Shwayder, MD

Fellow American Academies of Pediatrics

Fellow American Academies of Dermatology

Boarded, Pediatric Dermatology

Director, Pediatric Dermatology

Director, Dermatology Residency Program

Points of VIEW ON LINDANE

Information DOWNLOADS

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ADMINISTRATION

Len I. Sweet, PhD, MPH, Msc. Senior Health Scientist, Chemrisk. University of

ENVIRONMENTAL PROTECTION AGENCY

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CENTERS FOR DISEASE CONTROL AND PREVENTION

Tor Shwayder, MD, Director, Pediatric Dermatology, Director, Dermatology Residency MEDICAL & SCIENTIFIC **OPINIONS** Program, Henry Ford Hospital, Detroit, Michigan, June 2007.

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